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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,965	02/02/2004	Yuji Nakajima	040040	4559
23850 7590 08/19/2008 KRATZ, QUINTOS & HANSON, LLP 1420 K Street, N.W. Suite 400 WASHINGTON, DC 20005				
EXAMINER				
ROONEY, NORA MAUREEN				
ART UNIT		PAPER NUMBER		
1644				
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08/19/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/768,965

**Applicant(s)**

NAKAJIMA ET AL.

**Examiner**

NORA M. ROONEY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3, 6 and 9-40 is/are pending in the application.
- 4a) Of the above claim(s) 3, 6, 9-31, 34, 37 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-33, 35-36, 38-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicant's election without traverse of the species of dust-mite extract-Df allergens and Pfu protease S in the reply filed on 04/21/2008 is acknowledged.
2. Claims 3, 6, 9-31, 34 and 37-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09/28/2006 and 04/21/2008.
3. Claims 32-33, 35-36 and 39-40 are currently under examination as they read on an allergen inactivating method for dust mite extract-Df allergens by maintaining the allergens under a condition in which Pfu protease S and a denaturing agent exist.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 32-33, 35-36 and 39-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32 and 35 recite 'Df allergens' and claims 39 and 40 recite 'Pfu protease S.' These terms are indefinite because they only describe the allergen and protease of interest by arbitrary

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names, 'Df allergens' and 'Pfu protease S.' While the names may have some notion of the specificity of the allergen and protease, there is no recitation which distinctly claims them. For example, others in the field may isolate the same allergen and protease and give them entirely different names. Applicants should particularly point out and distinctly claim the 'Df allergens' and 'Pfu protease S' by claiming a sufficient number of characteristics associated with the allergens and protease. Claiming biochemical molecules by a particular name given to them by various workers in the field fails to distinctly claim the protein.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 32-33, 35-36 and 39-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: an allergen inactivating method for dust mite extract-Df allergens by maintaining the dust mite extract Df-allergens under a condition in which Pfu protease S or papain enzymes and urea or SDS exist, does not reasonably provide enablement for: an allergen inactivating method for dust mite extract -Df allergens by maintaining the allergens under a condition in which **an enzyme** and a denaturing agent exist, wherein the denaturing agent is **a surfactant** or urea of claim 32; wherein **the enzyme is a protease** of claim 33; wherein the protease is Pfu protease S of claim 39; an allergen inactivating method for dust mite extract-Df allergens by maintaining the allergen under a condition in which **an enzyme** and **a denaturing agent exist, wherein the denaturing agent is salt** of claim 35; wherein **the**

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**enzyme is a protease** of claim 35; and wherein the protease is Pfu protease S of claim 40. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification does not adequately disclose a dust mite extract-Df allergen inactivating method in which any enzyme and a denaturing agent exist because as is taught in throughout the art and specifically in Takai et al. (PTO-892; Reference U), dust mite extract inherently comprises the most potent indoor allergens Der p 1 and Der f 1, which are papain-like cysteine proteases. Therefore, dust mite extract is inherently exposed to protease enzymes at all times which increase the allergenicity of dust mite extract. Therefore, the specification is not enabled for a method of inactivating allergens in dust mite extract using any enzyme or any protease.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working

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examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

8. Claims 32-33, 35-36 and 39-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of: an allergen inactivating method for dust mite extract-Df allergens by maintaining the allergens under a condition in which Pfu protease S or papain enzymes and SDS or urea exist.

Applicant is not in possession of: an allergen inactivating method for dust mite extract - Df allergens by maintaining the allergens under a condition in which **an enzyme** and a denaturing agent exist, wherein the denaturing agent is **a surfactant** or urea of claim 32; wherein **the enzyme is a protease** of claim 33; wherein the protease is Pfu protease S of claim 39; an allergen inactivating method for dust mite extract-Df allergens by maintaining the allergen under a condition in which **an enzyme** and **a denaturing agent exist, wherein the denaturing agent is salt** of claim 35; wherein **the enzyme is a protease** of claim 35; and wherein the protease is Pfu protease S of claim 40.

Neither the exemplary embodiments nor the specification's general method appears to describe structural features, in structural terms that are common to the claimed genera. That is, the specification provides neither a representative number of species (enzymes, proteases, surfactants, salts) to describe the claimed genera, nor does it provide a description of structural features that are common to species (enzymes, proteases, surfactants, salts) that can be used in the claimed invention. As discussed above, the specification provides no structural description of enzymes, proteases, surfactants and salts other than ones specifically exemplified for use in the claimed invention. The specification's disclosure is inadequate to describe the claimed allergen inactivating method using any enzyme, protease, surfactant or salt.

Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3<sup>rd</sup> column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co., 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 32-33 and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Pernas et al. (PTO-892; Reference V).

Pernas et al. teaches an allergen inactivating method for dust mite extract -Df allergens Der p 1 and Der f 1 (enzymes, proteases) in SDS and EDTA (surfactant, salt) (In particular, abstract, page 974 1st full paragraph and last line of left column).

The reference teachings anticipate the claimed invention.

11. Claims 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (PTO-892; Reference W).

Chen et al. teaches an allergen inactivating method for dust mite extract -Df allergen Der p 1 (enzyme, protease) in NaOCl (salt) (In particular, page 1090 'Effect on other allergens' section).

The reference teachings anticipate the claimed invention.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)

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272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 17, 2008

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

/Eileen B. O'Hara/

Supervisory Patent Examiner

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